



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-18-18AXG; Docket No. number is CDC-2018-0086]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled "Maritime Illness Database and Reporting System (MIDRS)". The purpose of this data collection is to provide U.S.-bound passenger vessel operators an electronic reporting system to assist with their legal requirement to notify CDC of the number of passengers and crew members onboard their ship who have reportable acute gastroenteritis (AGE) as defined by federal quarantine regulations.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]** .

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0086 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Maritime Illness Database and Reporting System (MIDRS) - NEW - National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this new information collection request (ICR) is to request a three-year Paperwork Reduction Act (PRA) clearance for CDC's MIDRS surveillance system. MIDRS is currently approved under "Foreign Quarantine Regulations (42 CFR part 71)" (OMB Control No. 0920-0134, Expiration Date: 05/31/2019), sponsored by the National Center for Emerging and Zoonotic Infections Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Operationally, CDC has divided the responsibilities for enforcing foreign quarantine regulations between the Vessel Sanitation Program (VSP) and the Division of Global Migration and Quarantine (DGMQ). VSP takes the lead on overseeing acute

gastroenteritis (AGE) illness surveillance and outbreak investigation activities on passenger ships, while DGMQ monitors all non-AGE illnesses and deaths on passenger vessels as well as all diseases of public health concern on all other conveyances with international itineraries bound for the U.S. From 2012 to 2014 all ships submitted their AGE, non-AGE, and death reports to MIDRS using a common web portal; however program and reporting needs changed and dictated a need to move non-AGE illness and death reporting to a separate system. As of June 10, 2014, DGMQ has changed its routing method for receiving reports from ships. It no longer accepts non-AGE illness and death reports via MIDRS.

To complete the separation of shipboard quarantine and inspection functions across the two CDC national centers, the VSP seeks to transition all federally mandated AGE illness reporting activities to a new ICR housed within its own Center, since MIDRS is housed in and is used exclusively by VSP. DGMQ will continue to surveil non-AGE illnesses on cruise ships and all illnesses on other foreign to U.S. conveyances under Foreign Quarantine Regulations (OMB Control No. 0920-0134, expiration date 05/31/2019).

The MIDRS data collection system consists of a surveillance system that receives information electronically through a web-based reporting portal; data can also be submitted by phone,

email or fax and entered into MIDRS by VSP. AGE cases reported to MIDRS are totals for the entire voyage and do not represent the number of active AGE cases at any given port of call or at disembarkation. The AGE log, 72-hour food/activity history and other required documentation are completed and maintained on the ship.

Data collected will allow VSP to quickly detect AGE outbreaks, provide epidemiologic and sanitation guidance to stop the outbreak, craft public health recommendations to prevent future outbreaks, and monitor AGE illness trends to identify important changes over time.

There are two types of respondents for this data collection: cruise ship medical staff or other designated personnel who report AGE cases, and AGE cases who provide information for the 72-hour food/activity histories. Of note, VSP will not receive any information from or about the AGE cases; this information is collected and owned by the cruise line and maintained on the ship as part of the AGE case's medical record. VSP reviews these records during operational inspections to confirm they are available if needed, and if there is an AGE outbreak or report of unusual AGE illness for a particular voyage.

The total annualized time burden requested is 1,537 burden hours. A summary of the estimated annualized burden hours is shown in the table below.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Cruise ship medical staff or other designated personnel	71.21 (c) Gastrointestinal Illnesses reports 24 and 4 hours before arrival (MIDRS)	250	10	3/60	125
	71.21 (c) Recordkeeping - Gastrointestinal Illnesses reports 24 and 4 hours before arrival (MIDRS)	250	1	1/60	4
	71.21 (c) AGE Logs	250	10	10/60	417
	71.21 (c) Recordkeeping - medical records (AGE Logs)	250	1	1/60	4
	71.21(c) Interviews with AGE crew case cabin mates and immediate contacts to determine AGE illness status and documentation of	250	3	5/60	62.5

	interview dates/times				
	71.21 (c) Recordkeeping - medical records (Interviews with AGE crew case cabin mates and immediate contacts to determine AGE illness status and documentation of interview dates/times)	250	1	1/60	4
	71.21(c) Documentation of 3-day pre- embarkation AGE illness assessment for all crew members	250	5	3/60	62.5
	71.21 (c) Recordkeeping - medical records (Documentation of 3-day pre- embarkation AGE illness assessment for all crew members)	250	1	1/60	4
	71.21(c) Documentation of date/time of last symptom and clearance to return to work for food and nonfood employees	250	1	3/60	12.5

	71.21 (c) Recordkeeping - medical records (Documentation of date/time of last symptom and clearance to return to work for food and nonfood employees)	250	1	1/60	4
	71.21 (c) Recordkeeping - medical records (72 hour food/activity histories)	250	1	1/60	4
AGE passenger and crew cases	71.21 (c) 72-hour food/activity history	5,000	1	10/60	833
Total					1,537

Jeffrey M. Zirger,

Acting Chief,

Information Collection Review Office,

Office of Scientific Integrity,

Office of the Associate Director for Science,

Office of the Director,

Centers for Disease Control and Prevention.

[FR Doc. 2018-20808 Filed: 9/24/2018 8:45 am; Publication Date: 9/25/2018]